

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY : MDL NO. 1456
AVERAGE WHOLESALE PRICE :
LITIGATION : Master File No. 01-CV-12257-PBS
THIS DOCUMENT RELATES : Judge Patti B. Saris
TO ALL ACTIONS :
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**DEY INC.'S ANSWER TO PLAINTIFFS' FOURTH AMENDED
MASTER CONSOLIDATED CLASS ACTION COMPLAINT AMENDED
TO COMPLY WITH COURT'S CLASS CERTIFICATION ORDER**

Defendant Dey, Inc. ("Dey"), by its attorneys, Kelley Drye & Warren LLP, for its Answer to Plaintiffs' Fourth Amended Master Consolidated Complaint (the "AMCC"), states:

I. INTRODUCTION

1. Dey admits that Plaintiffs purport to bring this action as alleged in Paragraph 1 of the AMCC, but otherwise denies the allegations in Paragraph 1 of the AMCC.
2. To the extent the allegations in Paragraph 2 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraph 2 of the AMCC.
3. Dey denies the allegations in Paragraph 3 of the AMCC, except admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications.
4. Dey denies the allegations in Paragraph 4 of the AMCC.

5. Dey denies the allegations in Paragraph 5 of the AMCC.
6. Dey denies the allegations in Paragraph 6 of the AMCC.
7. Dey denies the allegations in Paragraph 7 of the AMCC.
8. Dey denies allegations in Paragraph 8 of the AMCC, except admits that Plaintiffs have filed attachments to the AMCC.

II. JURISDICTION AND VENUE

9. Dey denies the allegations in Paragraph 9 of the AMCC.
- 10-12. Dey denies the allegations in Paragraphs 10 through 12 of the AMCC, and refers the Court to the Order dated April 30, 2002 as the best evidence of its contents.

III. PARTIES

13. Dey is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of the AMCC and, therefore, denies those allegations.
- 14-61. Dey is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 14 through 61 of the AMCC and, therefore, denies those allegations. Further, Dey denies that the individuals named in the referenced allegations are appropriate class representatives.

62-69. Dey denies the allegations in Paragraphs 62 through 69 of the AMCC.

- 70-102. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 70 through 102 of the AMCC insofar as they are directed to other defendants and, therefore, denies those allegations.

103. Dey admits that it is a Delaware corporation with its principal place of business located at 2751 Napa Valley Corporate Drive, Napa, California and that Merck KGaA is a corporation organized and existing pursuant to the laws of the Federal Republic of Germany and

is the ultimate parent of Dey. Dey denies the remaining allegations in Paragraph 103 of the AMCC.

104. Dey admits that it is a specialty pharmaceutical company that develops, manufactures, and markets certain generic drugs used in the treatment of, among other things, respiratory diseases and allergies. Dey also admits that it had net sales in 1998 of \$266 million. Dey denies the remaining allegations in Paragraph 104 of the AMCC.

105. Dey admits the allegations of Paragraph 105 of the AMCC.

106. Dey admits the allegations of Paragraph 106 of the AMCC.

107. Dey admits that it is a specialty pharmaceutical company that manufactures, among other pharmaceuticals, ipratropium bromide, metaproterenol sulfate, and Accuneb. Dey denies the remaining allegations in Paragraph 107 of the AMCC.

108-144. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 108 through 144 of the AMCC insofar as they are directed to other defendants and, therefore denies those allegations.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

145. Dey denies the allegations in Paragraph 145 of the AMCC.

146. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 146 of the AMCC and, therefore, denies those allegations, except admits patients receive drugs from physicians, pharmacies, and other health care providers.

147. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 147 of the AMCC and, therefore, denies those allegations.

Answering further, Dey denies that it was “aware” of the actions and knowledge of the Medicare Program and unspecified “end payors.”

148. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 148 of the AMCC and, therefore, denies those allegations, except Dey admits that pharmaceutical industry pricing publications periodically report AWPs for prescription medicines sold in the United States.

149. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 149 of the AMCC and, therefore, denies those allegations and refers the Court to the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 149 of the AMCC as the best evidence of their contents.

150. Dey denies the allegations in Paragraph 150 of the AMCC.

151. Dey denies the allegations in Paragraph 151 of the AMCC.

152. Dey denies the allegations in Paragraph 152 of the AMCC.

153. Dey denies the allegations in Paragraph 153 of the AMCC.

154. Dey denies the allegations in Paragraph 154 of the AMCC.

155-157. Dey admits the allegations in Paragraphs 155 through 157 of the AMCC.

158. Dey denies the allegations in Paragraph 158 of the AMCC, and refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.

159. Dey denies the allegations in Paragraph 159 of the AMCC.

160. Dey denies the allegations in Paragraph 160 of the AMCC, and refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.

161. Dey denies the allegations in Paragraph 161 of the AMCC, and refers the Court to the Program Memo AB-99-63 cited in Paragraph 161 of the AMCC as the best evidence of its contents.

162. Dey denies the allegations in Paragraph 162 of the AMCC, and refers the Court to the Program Memo AB-99-63 cited in Paragraph 162 of the AMCC as the best evidence of its contents.

163-164. Dey admits the allegations in Paragraphs 163 through 164 of the AMCC.

165. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 165 of the AMCC and, therefore, denies those allegations, except admits that there are no government regulations describing how AWPs are calculated, nor any other statutory or regulatory definitions or descriptions of AWPs, and that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications.

166-167. Dey denies the allegations in Paragraphs 166 and 167 of the AMCC, and refers the Court to the April 2003 OIG Guidance cited in Paragraphs 166 and 167 of the AMCC as the best evidence of its contents.

168. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 168 of the AMCC and, therefore, denies those allegations, except admits it is aware that certain investigations are occurring.

169-170. Dey denies the allegations in Paragraphs 169 and 170 of the AMCC, and refers the Court to the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 169 and 170 of the AMCC as the best evidence of its contents.

171-172. To the extent the allegations in Paragraphs 171 through 172 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 171 through 172 of the AMCC, except admits it is aware that certain investigations are ongoing.

173. To the extent the allegations in Paragraph 173 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 173, except admits that it provided AWPs to the pharmaceutical compendia.

174-197. To the extent the allegations in Paragraphs 174 through 197 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 174 through 197 of the AMCC.

198. Dey denies the allegations in Paragraph 198 of the AMCC.

199. Dey denies the allegations in Paragraph 199 of the AMCC.

200. To the extent the allegations in Paragraph 200 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 200.

201. Dey denies the allegations in Paragraph 201 of the AMCC.

202. Dey denies the allegations in Paragraph 202 of the AMCC, and refers the Court to the complaint cited in Paragraph 202 as the best evidence of its contents.

203. Dey denies the allegations in Paragraph 203 of the AMCC.

204. To the extent the allegations in Paragraph 204 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 204.

205. To the extent the allegations in Paragraph 205 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey respectfully refers the Court to the 2003 CMS document cited in Paragraph 205 of the AMCC as the best evidence of its contents. Dey denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. Dey admits that it sells its medicines in a competitive market and, as such, takes steps to keep certain information relating to its medicines confidential. Dey denies the remaining allegations in Paragraph 205 of the AMCC.

206-209. To the extent the allegations in Paragraphs 206 through 209 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 206 through 209 of the AMCC.

210-212. Dey denies the allegations in Paragraphs 210 through 212 of the AMCC.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

213. To the extent the allegations in Paragraph 213 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 213 of the AMCC.

214-336. The allegations in Paragraphs 214 through 336 of the AMCC are directed to another defendant and require no response from Dey. To the extent allegations in Paragraphs 214 through 336 of the AMCC are deemed to require a response, they are denied.

337. Dey denies the allegations in Paragraph 337 of the AMCC.

338. Dey denies the allegations in Paragraph 338 of the AMCC, except admits that the governmental agencies listed in Paragraph 338 of the AMCC have conducted investigations concerning pricing in the pharmaceutical industry and that Dey, among others, has participated in certain of such investigations.

339. Dey denies the allegations in Paragraph 339 of the AMCC, and refers the Court to the editions of the *Red Book* and the September 25, 2000, letter from Representative Bliley to Nancy-Ann DeParle as the best evidence of their contents.

340-341. Dey denies the allegations in Paragraphs 340 and 341 of the AMCC, except admits that the Attorneys General of Texas, West Virginia and Connecticut have commenced actions against Dey, which have since been discontinued as to Dey, and refers the Court to the pleadings in those actions as the best evidence of their contents.

342. Dey denies the allegations in Paragraph 342 of the AMCC, except admits that it reported certain pricing information for its medicines to pharmaceutical industry pricing publications during the purported Class Period and that it reported suggested AWP prices, and

further admits that it prepared the document cited in Paragraph 342(a) of the AMCC (DL-CA 00120), but Dey states that this document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from this document are accurate. Dey denies that it prepared the document cited in Paragraph 342(b) of the AMCC (DL-CA 00080), except Dey admits that the referenced, handwritten notations on DL-CA 00080 were made by a Dey employee.

343. Dey denies the allegations in Paragraph 343 of the AMCC, except admits that it prepared the documents cited in Paragraph 343(a) and 343(b) of the AMCC (DL-TX-0014029 and DL-TX-0014439), but Dey states that these documents are the best evidence of their contents and denies that the conclusions Plaintiffs draw from these documents are accurate.

344-346. To the extent the allegations in Paragraphs 344 through 346 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey states that the reports published by the OIG (OEI-03-01-00410, March 2002), cited and referred to in Paragraphs 344 and 345 of the AMCC, and the report published by the GAO (*see* "MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost"), cited in Paragraph 346 of the AMCC, are the best evidence of their contents, but Dey denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement or conclusion contained in these documents. Dey admits that albuterol sulfate is a multiple-source drug manufactured and/or marketed by Dey. Dey denies the remaining allegations in Paragraphs 344 through 346 of the AMCC.

347. To the extent the allegations in Paragraph 347 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations

and, therefore, denies those allegations. Dey states that the report published by the DHHS cited in Paragraph 347 of AMCC is the best evidence of its contents, but Dey denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement or conclusion contained in such report. Dey denies the remaining allegations in Paragraph 347.

348. To the extent the allegations in Paragraph 348 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies that the document cited as the source for "Table 1" in paragraph 348 of the AMCC is a document prepared by Dey and further denies that this document reflects any conduct by or knowledge of Dey. Dey further denies that "Table 1" in paragraph 348 of the AMCC accurately reflects the contents of the cited document (DL-TX 0011179), and otherwise denies the allegations in Paragraph 348.

349-350. To the extent the allegations in Paragraphs 349 and 350 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that it prepared the document cited in Paragraph 350 of the AMCC (DL-TX-0004775), but Dey states that this document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from this document are accurate. Dey denies the remaining allegations in Paragraphs 349 and 350.

15-351. To the extent the allegations in the Paragraph erroneously denominated "15" and Paragraph 351 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that it prepared the

document cited in the Paragraph erroneously denominated "15" of the AMCC (DL-TX-0024844), but Dey states that this document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from this document are accurate. Dey denies the remaining allegations in the paragraph erroneously denominated "15" and Paragraph 351 of the AMCC.

352-501. The allegations in Paragraphs 352 through 501 of the AMCC are directed to another defendant and require no response from Dey. To the extent allegations in Paragraphs 352 through 501 of the AMCC are deemed to require a response, they are denied.

VI. PLAINTIFFS' CLAIM FOR DAMAGES

502. Dey denies that Plaintiffs have suffered damages or injuries as alleged in Paragraph 502 of the AMCC. Dey denies having knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 502 of the AMCC and, therefore, denies those allegations.

VII. CLASS ALLEGATIONS FOR THE PURPORTED "AWP PAYOR CLASS"

503-512. Dey denies the allegations in Paragraphs 503 through 512 of the AMCC.

COUNT I (RICO)

513-541. The Court dismissed Count I in its Order dated February 25, 2004. Accordingly, Dey does not respond to Paragraphs 513 through 541 of the AMCC. To the extent a response is required, Dey denies all allegations contained within Count I of the AMCC.

COUNT II (RICO)

542. Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 541 of the AMCC.

543. Dey denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Dey under Count II, and Dey denies the remaining allegations in Paragraph 543 of the AMCC.

544. Dey denies the allegations in Paragraph 544 of the AMCC.

545. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 545 and, therefore, denies those allegations.

546-550. To the extent the allegations in Paragraphs 546 through 550 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey states that the unidentified "industry report" cited in Paragraph 550 of the AMCC is the best evidence of its contents. Dey denies that Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement or conclusion. Dey denies the remaining allegations in Paragraphs 546 through 550 of the AMCC.

551-573. To the extent the allegations in Paragraphs 551 through 573 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 551 through 573 of the AMCC.

574. Dey denies the allegations in Paragraph 574 of the AMCC.

COUNT III (DECLARATORY RELIEF)

575. Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 574 of the AMCC in response to Paragraph 575 of the AMCC and otherwise denies the allegations in Paragraph 575 of the AMCC.

576. To the extent the allegations in Paragraph 576 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 576 of the AMCC.

577-578. Answering the first sentence of Paragraph 577 of the AMCC, Dey refers to and incorporates its response to Paragraph 576 of the AMCC. To the extent the allegations in Paragraphs 577 and 578 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 577 and 578 of the AMCC.

COUNT IV (CONSUMER PROTECTION STATUTES)

579. Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 578 of the AMCC in response to Paragraph 579 of the AMCC and otherwise denies the allegations in Paragraph 579 of the AMCC.

580. Dey admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the AMCC as alleged in Paragraph 580, but Dey denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Dey under Count IV. Dey denies the remaining allegations in Paragraph 580 of the AMCC.

581. To the extent the allegations in Paragraph 581 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that its principal place of business is located in Napa, California. Dey admits that certain states have enacted consumer protection laws, but Dey denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Dey denies the remaining allegations in Paragraph 581 of the AMCC.

582-586. To the extent the allegations in Paragraphs 582 through 586 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 582 through 586 of the AMCC.

COUNT V (VIOLATION OF CONSUMER PROTECTION LAWS)

587. Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 586 of the AMCC in response to Paragraph 587 of the AMCC and otherwise denies the allegations in Paragraph 587 of the AMCC.

588. To the extent the allegations in Paragraph 588 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 588 of the AMCC.

589. To the extent the allegations in Paragraph 588 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 589 of the AMCC.

590-593. Dey denies the allegations in Paragraphs 590 through 593 of the AMCC.

594-595. Dey is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 594 and 595 and, therefore, denies those allegations.

COUNT VI (VIOLATION OF CONSUMER PROTECTION LAWS)

596. Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 595 of the AMCC in response to Paragraph 596 of the AMCC and otherwise denies the allegations in Paragraph 596 of the AMCC.

597-601. denies the allegations in Paragraphs 597 through 601 of the AMCC.

602-603. Dey is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 602 and 603 and, therefore, denies those allegations.

COUNT VII (VIOLATION OF CONSUMER PROTECTION LAWS)

604. Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 603 of the AMCC in response to Paragraph 604 of the AMCC and otherwise denies the allegations in Paragraph 604 of the AMCC.

605-608. Dey denies the allegations in Paragraphs 605 through 608 of the AMCC.

609. Dey denies the allegations in Paragraph 609 of the AMCC and respectfully refers the Court to the referenced ruling as the best evidence of its terms.

610. Dey denies the allegations in Paragraph 610 of the AMCC.

611-613. The extent that Paragraphs 611 though 613 of the AMCC state legal conclusions, no response is required. To the extent the allegations in Paragraphs 611 through 613 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey further denies the remaining allegations in Paragraphs 611 through 613 of the AMCC.

COUNT IX (CIVIL CONSPIRACY)

614. Answering Paragraph 614 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 613 of the AMCC.

615. Dey denies that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. Dey denies having knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 615 of the AMCC and, therefore, denies those allegations.

616-619. To the extent the allegations in Paragraphs 616 through 619 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 616 through 619 of the AMCC.

620-621. Dey denies the allegations in Paragraphs 620 and 621 of the AMCC.

UNNUMBERED “WHEREFORE” PARAGRAPH AND REQUEST FOR JURY TRIAL

Dey denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and “WHEREFORE” paragraph following Paragraph 621 of the AMCC.

AFFIRMATIVE AND OTHER DEFENSES

First Defense

Plaintiffs and the putative class fail to state a claim against Dey upon which relief may be granted.

Second Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Third Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the filed rate doctrine.

Fourth Defense

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Dey as alleged in the AMCC.

Fifth Defense

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against Dey based on the AMCC pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

Sixth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions of the States to the extent applicable to this action.

Seventh Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Dey in judicial, legislative or administrative proceedings of any kind or at any level of government.

Eighth Defense

Plaintiffs and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

Ninth Defense

Any and all actions taken by Dey with respect to any of the matters alleged in the AMCC were taken in good faith and in accordance with established industry practice.

Tenth Defense

Plaintiffs and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

Twelfth Defense

Plaintiffs' and the putative class' claims against Dey are barred because Dey has complied with all applicable regulations of the federal and state governments.

Thirteenth Defense

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, by the applicable statutes of limitations and repose.

Fourteenth Defense

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, and unclean hands.

Fifteenth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate Dey's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

Sixteenth Defense

Plaintiffs and the putative class fail to state with particularity facts to support the fraud and/or fraudulent concealment allegations against Dey contained in the AMCC.

Seventeenth Defense

Plaintiffs and the putative class failed to plead with particularity their multi-source medicine allegations against Dey in the AMCC.

Eighteenth Defense

Plaintiffs' and the putative class' RICO claims against Dey are barred, in whole or in part, due to their failure to plead facts showing: (i) that Dey and the PBMs are ongoing organizations whose members function as continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981); (ii) the existence of a RICO enterprise as required by 18 U.S.C. § 1962(c); and (iii) that Dey conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

Nineteenth Defense

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against Dey as required by Fed. R. Civ. P. 9(b), including but not limited to the failure to allege a concerted action or a coercive conspiracy.

Twentieth Defense

Plaintiffs' and the putative class' civil conspiracy claims against Dey are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 364 (D. Mass. 2002).

Twenty-First Defense

Dey denies that Plaintiffs and the putative class have valid consumer protection claims against Dey under the laws of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington or any other State whose law is or becomes

relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Dey pleads all available defenses under the Acts.

Twenty-Second Defense

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against Dey under any state consumer protection law.

Twenty-Third Defense

Any allegedly fraudulent statement or conduct of Dey was not consumer-oriented as required under certain consumer protection laws.

Twenty-Fourth Defense

Plaintiffs' and the putative class' claims against Dey for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Twenty-Fifth Defense

Plaintiffs' and the putative class' claims for injunctive relief against Dey are barred by the doctrines of *in pari delicto* and/or unclean hands.

Twenty-Sixth Defense

This action cannot be maintained as a class action because the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.

Twenty-Seventh Defense

This action cannot be maintained as a class action because the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences.

Twenty-Eighth Defense

This action cannot be maintained as a class action because the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23.

Twenty-Ninth Defense

This action cannot be maintained as a class action because the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity.

Thirtieth Defense

This action cannot be maintained as a class action because class certification would violate Dey's rights provided by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the analogous provisions of the Constitutions of the States, including but not limited to Dey's right to procedural and substantive safeguards, which include traditional defenses to liability.

Thirty-First Defense

Third party payor plaintiffs' and third party payor putative class members' claims against Dey are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price on the ground that third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums.

Thirty-Second Defense

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine

directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

Thirty-Third Defense

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, due to their failure to join indispensable parties.

Thirty-Fourth Defense

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the AMCC.

Thirty-Fifth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties.

Thirty-Sixth Defense

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Dey.

Thirty-Seventh Defense

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the AMCC.

Thirty-Eighth Defense

Dey is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

Thirty-Ninth Defense

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by Dey after the filing of Plaintiffs' original Complaint.

Fortieth Defense

Any damages recovered by the Plaintiffs and the putative class from Dey must be limited by the applicable statutory ceilings on recoverable damages.

Forty-First Defense

Plaintiffs and the putative class fail to allege facts or a cause of action against Dey sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

Forty-Second Defense

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

Forty-Third Defense

Dey's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

Forty-Fourth Defense

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, because Dey did not make any false statements to Plaintiffs or to any members of the putative class members. As to any statement asserted against Dey that Plaintiffs and the putative class allege to be false or misleading, Dey had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Forty-Fifth Defense

Plaintiffs and the putative class lack standing to bring their RICO claims against Dey because they cannot show Dey directly caused their alleged injuries as required by 18 U.S.C. § 1964(c); *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992); *Platten v. HG Berm. Exempted Ltd.*, 437 F.3d 118, 132 (1st Cir. 2006); and *George Lussier Enters. v. Subaru of New Eng., Inc.*, 393 F.3d 36, 51 (1st Cir. 2004) .

Forty-Sixth Defense

Plaintiffs' and the putative class' civil conspiracy claims against Dey are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1st Cir. 1994) and *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and/or by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).

Forty-Seventh Defense

Dey's conduct was not "knowing," "deceptive," "misleading," "unlawful," a "misrepresentation" or "illegal" as required under certain state consumer protection laws, including without limitation to any of the State consumer protection laws alleged in this

Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Forty-Eighth Defense

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of Dey as required under certain state consumer protection laws, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Forty-Ninth Defense

To the extent the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation do not recognize a private right of action, Plaintiffs are not entitled to relief under the applicable statutes.

Fiftieth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation limit claims to those brought by “consumers,” Plaintiffs are not entitled to relief under the applicable statutes.

Fifty-First Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs to send a written demand for relief to Defendants prior to filing a Complaint, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

Fifty-Second Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs to attempt Alternative Dispute Resolution prior to filing a Complaint, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

Fifty-Third Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs provide notice of the practice at issue to the relevant State Attorney General, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

Fifty-Fourth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation limit Plaintiffs' available remedies, Plaintiffs are not entitled to their requested relief under the applicable statutes.

Fifty-Fifth Defense

Plaintiffs' and the putative class' claims against Dey under the various state consumer protection and consumer fraud statutes are barred in whole or in part to the extent those statutes do not govern conduct that is predominantly interstate in nature.

Fifty-Sixth Defense

Plaintiffs' and the putative class' claims against Dey under the various state unfair trade, unfair competition, consumer protection and consumer fraud statutes are barred to the extent (1) those claims represent an impermissible circumvention of the states' antitrust statutes; and (2)

those statutes apply only to deceptive or misleading conduct and/or govern only consumer transactions.

Fifty-Seventh Defense

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

Fifty-Eighth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against Dey: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the AMCC are legally insufficient to support a claim for punitive damages against Dey; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give Dey prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Dey' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitutions and the constitutions of any applicable states' laws; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Dey' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Dey for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Dey' medicines would constitute impermissible multiple

punishments for the same wrong, in violation of Dey' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of any applicable states' laws; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Dey' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' law; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Dey the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Dey' rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Ninth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against Dey cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive

damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Dey, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is not properly instructed regarding Plaintiff's and the putative class' burden of proof with respect to each and every element of a claim for punitive damages, or (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Dey's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

Sixtieth Defense

To the extent punitive damages are sought, Plaintiff's and the putative class' claim for punitive damages against Dey cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Dey's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Dey's right not to be subjected to an excessive award; and (3) be improper under the constitutions, common law and public policies of any applicable states' laws.

Sixty-First Defense

Plaintiffs' and the putative class members' claims are barred, in whole or in part, because they conflict with federal statutes and regulations that comprise a comprehensive regulatory regime governing the amounts paid to providers for Medicare Part B-covered drugs.

Sixty-Second Defense

Plaintiffs and the putative class members are not entitled to the relief requested in the Complaint because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.

Sixty-Third Defense

Plaintiffs and the putative class members are barred from recovery because the representations and actions alleged by Plaintiffs were not and are not material, in that they were not and are not likely to affect the decisions or conduct of Plaintiffs and putative class members, or to have caused consumers or Third Party Payors to have chosen differently, but for such alleged representations or actions, in light of the information available and known to consumers and Third Party Payors, and in that the alleged representations and actions were not likely to mislead consumers or Third Party Payors acting reasonably under the circumstances.

Sixty-Fourth Defense

Plaintiffs' and putative class members' claims against Dey under the various state unfair and deceptive trade practice or consumer protection or consumer fraud statutes are barred in whole or in part because excess-provider-profit claims are inherently speculative and subjective and not subject to judicial resolution.

Sixty-Fifth Defense

Plaintiffs' and putative class members' claims fail, in whole or in part, because of improper claim splitting.

Sixty-Sixth Defense

Plaintiffs' and putative class members' antitrust claims against Dey are barred in whole or in part because (1) they have not suffered any anti-trust injury; (2) they lack standing; and/or (3) the alleged conspiracy does not make economic sense and is economically implausible.

Sixty-Seventh Defense

Any alleged restraints complained of in the AMCC are ancillary to legitimate, pro-competitive activity.

Sixty-Eighth Defense

Plaintiffs and putative class members are precluded from recovery because the representations and actions alleged by Plaintiffs were not intended to deceive Plaintiffs and the putative class members.

Sixty-Ninth Defense

Dey is not liable to Plaintiffs and the putative class members because it had no duty to disclose the information allegedly not disclosed.

Seventieth Defense

Plaintiffs' and the putative class members' claims against Dey are barred, in whole or in part, by the doctrines of assumption of the risk and/or comparative fault or negligence.

Seventy-First Defense

Dey adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Seventy-Second Defense

Dey hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense. Dey also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and/or any other State law which is or becomes relevant in the course of this multidistrict litigation.

Seventy-Third Defense

To the extent equitable relief is sought, such claims cannot be sustained because Plaintiffs and the putative class have an adequate remedy at law.

Seventy-Fourth Defense

Plaintiffs' and the putative class members' claims against Dey are barred because the relief sought is within the exclusive jurisdiction of the United States Department of Health and Human Services, Center for Medicare and Medicaid Services and, therefore, the Court lacks jurisdiction to grant the relief sought.

WHEREFORE, Dey respectfully requests that the Court:

1. Dismiss the Fourth Amended Master Consolidated Class Action Complaint with prejudice and enter judgment in favor of Dey and against Plaintiffs;
2. Award Dey its costs, expenses, and attorneys' fees; and
3. Grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: May 15, 2006

Respectfully submitted,

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Attorneys for Defendant Dey, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of May, 2006, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to LexisNexis File & Serve for posting and notification.

A handwritten signature in black ink, appearing to be a stylized 'K' or 'M', is written over a horizontal line.

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